

AP  
JFW

**CERTIFICATE OF FIRST CLASS MAIL**

I hereby certify that this paper or fee is being deposited with the United States Postal Service by First Class Mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Name of Depositor:

Eileen Sheffield

Date:

6/2/05

Signature of Depositor

Eileen Sheffield

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Applicant : Hiles, et al.

Serial No. : 09/325,095

Filed : June 3, 1999

For : METHODS FOR DETERMINING EXPRESSION OF A P13 KINASE GENE

Art Unit : 1645

Examiner : J. Hines

June 2, 2005

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450  
MS: Appeal Brief Patents

**REPLY BRIEF TO EXAMINER'S ANSWER  
(37 CFR §41.41)**

Pursuant to 37 C.F.R. §41.41, Applicants hereby respond to the Examiner's Answer dated April 8, 2005.

Applicants note with appreciation that the written description rejection under 35 U.S.C. §112, first paragraph, and the rejections under 35 U.S.C. §112, second paragraph for omission of essential steps and indefiniteness have been withdrawn.

A. **The Rejection of Claims 51-58 and 60-61 Under 35 U.S.C. § 112, First Paragraph, for Allegedly Containing New Matter is Improper, and Should be Reversed**

The Examiner has maintained the new matter rejection of claims 51-58 and 60-61 under 35 U.S.C. § 112, first paragraph. The Examiner argues that there is no disclosure in the specification that the invention includes a method for determining gene expression using the specific nucleotide sequences. The Examiner also states that there is no disclosure that determining hybridization will act as a determination of gene expression, nor does it teach that the various hybridization and PCR techniques disclosed should be applied to determine gene expression. Further, as support for this rejection, the Examiner points to a lack of an outline, protocol or experiments for determining hybridization to determine gene expression as claimed.

The specification adequately describes hybridization, one type of which is the well known Polymerase Chain Reaction (PCR) (pages 38-41). The experiments described in the specification involving PCR use cDNA created from mRNA (see, e.g., page 38, lines 8-17 and line 21; page 39, lines 18-24), and in order to have mRNA, gene expression must have already occurred. This is based on known principles of molecular biology. Thus, one of ordinary skill in the art would have known that gene expression could be determined in this manner, since the existence of mRNA means gene expression has occurred.

Furthermore, Applicants reiterate that they claim a method for determining expression of a gene, comprising contacting a sample with a nucleic acid molecule which hybridizes specifically to a transcript of the gene, and determining hybridization as a determination of gene expression. As discussed in previous submissions, protein expression is not required to demonstrate gene expression. The first step in gene expression is formation of a transcript. Since Applicants are measuring hybridization to a transcript, this means that gene expression has

already occurred. One of skill in the art would have known that determining hybridization to a transcript of the gene can be used to determine gene expression, since the presence of a transcript means that gene expression has already occurred.

**B. Conclusion**

For the reasons set forth supra, it is believed that the rejection under 35 U.S.C. § 112, first paragraph is improper and should be reversed.

No fees are believed due in connection with this response. In the event any additional fees are due, authorization is hereby given to charge deposit account no. 50-0624.

Respectfully submitted,

FULBRIGHT & JAWORSKI, L.L.P.

A handwritten signature in black ink, appearing to read "Norman D. Hanson", is written over a horizontal line.

Norman D. Hanson, Esq.  
Registration No. 30,946

666 Fifth Avenue  
New York, NY 10103  
(212) 318-3000  
(212) 318-3400 (fax)